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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

33677.00600US

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on _____

Signature _____

Typed or printed name _____

Application Number

09/382,837

Filed

8/25/1999

First Named Inventor

Gary E. Borodic

Art Unit

1644

Examiner

Ewoldt, Gerald R.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record. 47,304
Registration number _____☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Enrique D. Longton

Typed or printed name

(202) 835-7525

Telephone number

April 13, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. Application Serial No. 09/382,837
Attorney Docket No.: 33677-00600
Pre-Appeal Brief Request for Review

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Gary E. BORODIC)	
)	
Application Serial No.: 09/382,837)	Group Art Unit: 1644
)	
Filed: August 25, 1999)	Examiner: G. R. Ewoldt, Ph.D.
)	
Title: <i>Chemodenervating Pharmaceutical As An</i>)	
<i>Anti-Inflammatory Agent</i>)	

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In response to the Final Office Action mailed October 13, 2005, Applicant respectfully submits the following Pre-Appeal Brief Request for Review. A Notice of Appeal is filed concurrently herewith with the required fee. This Pre-Appeal Brief Request for Review is being timely filed with a petition for a two-month extension of time with the required fee. Applicant previously filed a petition for a one-month extension of time, with the required fee on February 13, 2006.

Applicant respectfully submits that the rejections of record are clearly improper because essential elements required to establish a *prima facie* case have been omitted. The rejections of record are based on errors in facts and should be withdrawn. Applicant canceled claims and provided a detailed explanation of the bases for traversing the pending rejections in the

Amendment After Final filed February 13, 2006. The Advisory Action mailed March 30, 2006 summarily dismissed the Amendment After Final with a one sentence note indicating "Applicant has submitted 33 pages of new arguments that would comprise further consideration." Entry of the amendment, withdrawal of the outstanding rejections and allowance of the claims is requested.

***The Rejection of Claims 1, 5-8, 24, 25, 42, 43 and 46-57
under 35 U.S.C. § 112 First Paragraph***

Claims 1, 5-8, 24, 25, 42, 43 and 46-57 stand rejected under 35 U.S.C. § 112, first paragraph, because it is alleged that the specification does not enable a method of reducing inflammation without causing muscle weakness. Applicant respectfully asserts that the rejection is improper because: (1) the Office has not met its burden of establishing a *prima facie* case of lack of enablement because four of the eight Wands factors have not been addressed by the Office; (2) no experimentation would be required to practice the claimed invention and the Office bases its determination of lack of enablement on conclusory statements that ignore or discount what is taught in the specification; and (3) the Office has not provided any evidence to support its position that the statements made in the specification should not be accepted. This rejection was discussed at length in the Amendment After Final filed February 13, 2006 at pages 8-20.

The Office disregards the teachings of the instant specification without providing any basis for doing so. Specifically, while the Office acknowledges that "reduced inflammation was noted," it states that this was "only as a side effect of treatment for other disorders." See October 13, 2005 Office Action at page 3. The Office states that none of the examples disclose a dose of

botulinum toxin sufficient to reduce inflammation but less than that necessary to cause substantial muscle weakness. In fact, the specification clearly discloses anti-inflammatory effects and reduced inflammatory response in various patients. See, for example, Figures 1, 2 and 4, and pages 10, 11, 13-15 of the specification. The specification further discloses that the levels used to reduce inflammation are less than the levels that cause muscle weakness - see Figure 6 (the total doses used to treat blepharoconjunctivitis are below that necessary to cause weakness or eyelid closure) and page 19, line 4 (reduced inflammation shown below the dose range to treat torticollis-cervical dystonia).

Further, the specification clearly discloses specific doses of botulinum toxin that can be used by a skilled artisan to practice “a method of reducing inflammation without causing muscle weakness.” For example, page 3 (Summary of the Invention - “botulinum toxin in doses from $1/3^{\text{rd}}$ to several orders of magnitude less than those associated with treatment of regional movement diseases has been effective to reduce inflammation”); page 4 (“Typical minimum effective doses range from 0.5-5 units as opposed to 20-600 units used for treatment of movement disorders”); and page 19 (“Minimum doses range between 0.6 units to 15 units and are far lower than that required to produce regional weakness”) of the specification each teach doses that reduce inflammation but do not cause muscle weakness. Applicant respectfully submits that the specification enables the full scope of the claims.

The Rejection of Claims 10-12, 17-19 and 21-23 under 35 U.S.C. § 103(a)

Claims 10-12 stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,063,768 in view of the Merck Manual (1992). This rejection was

addressed at length in Applicant's Amendment of February 13, 2006 at pages 20-23. The rejection is improper because it includes clear errors and omits essential elements needed to establish a *prima facie* rejection.

For example, the Office acknowledges the '768 patent does not teach reducing inflammation due to blepharoconjunctivitis, hay fever, rhinitis, or type 1 hypersensitivity, but alleges that one of skill in the art would substitute such inflammatory disorders (blepharoconjunctivitis, hay fever, rhinitis, and type 1 hypersensitivity that are amenable to treatment by anti-inflammatory agents, as taught by the Merck Manual) (see October 13, 2005 Office Action at page 7). But, nowhere in any of the references is there any teaching or suggestion of "allergic blepharoconjunctivitis" or "a periocular area," nor are there any teachings of "hay fever," "allergic forms of eczema," "urticaria," or "inflammatory bowel disease." Thus, the rejection is deficient because specific limitations recited in the claims are not taught in the references. Neither is there any motivation to combine the references.

***The Rejection of Claims 1, 5-8, 10-12, 17-19 and 21-25 under
35 U.S.C. § 112 First Paragraph***

Claims 1, 5-8, 10-12, 24, 25 and 42-57 stand rejected under 35 U.S.C. § 112, first paragraph, because the claims allegedly lack written description support in the specification. This rejection was addressed at length in the After Final Amendment filed February 13, 2006 at pages 23-38.

The rejection is improper because Applicant has explained in great detail where in the specification support may be found for the claims. The Office has not addressed Applicant's arguments or indicated why the claims lack support.

Declaration

The Declaration stands objected to. Applicant filed a Preliminary Amendment dated May 14, 2001, amending the specification to properly recite the priority claim to Provisional Application No. 60/097,846, and submitted a substitute Declaration (Form PTO/SB/01) on February 13, 2006. Withdrawal of the objection is requested.

CONCLUSION

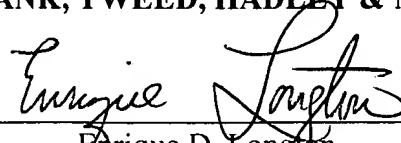
Applicant believes that the above-referenced application is in condition for allowance. Reconsideration and withdrawal of the outstanding rejections and notice of allowance to that effect is respectfully requested.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 13-3250. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

MILBANK, TWEED, HADLEY & McCLOY LLP

By: _____


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Reg. No. 47,304

Dated: April 13, 2006

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